PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	**Paul H. Burmeister, Charles L. Euteneuer, Brian J. Brown, Paul J. Fordenbacher, Anthony C. Vrba**
Application No.:	**09/427291**
Filed:	**October 26, 1999**
For:	**IMPROVED TISSUE SUPPORTING DEVICES**
Examiner:	**Paul Prebilic**
Group Art Unit:	**3731**

Mail Stop Appeal Brief
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2N-4944-US04

BRIEF ON APPEAL

This is a Brief on Appeal for the above-identified application in which claims 22-32 and 34-35 were rejected for a second time in an Office Action mailed August 19, 2003. A Notice of Appeal was filed in this case on January 19, 2004. The fees required under §1.17(f) and any required petition for extension of time for filing this brief therefor are dealt with in the accompanying Transmittal of Appeal Brief. This brief is transmitted in triplicate in accordance with 37 C.F.R. §1.192(a).

(1) Real Party in Interest

The application is assigned to SciMed Life Systems, Inc., One SciMed Place, Maple Grove, MN 55311-1566, a Minnesota Corporation and a subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts, 01760-1537, a Delaware Corporation.

(2) Related Appeals and Interferences

No related appeals or interferences are pending. In a preliminary amendment filed in this case on October 26, 1999, Applicant has requested that an interference be declared with Roubin, et al, US 5,827,321 issued October 27, 1998.

(3) Status of Claims

Claims 22-32 and 34-35 are pending in the application. Claims 22-32 and 34-35, reproduced in Appendix A, have been twice rejected and are the subject of this appeal.

(4) Status of Amendments

All claims amendments made to-date have been entered. An amendment updating the status of the parent application and identifying the relevant PCT filing date of that application was submitted in an Amendment filed Jan 19, 2004, and is presumed to have been entered.

(5) Summary of the Invention

The invention relates to stents for intravascular implantation. As stated in the abstract and elsewhere, the stents of the invention "allow for initial self expansion and subsequent deformation to a final enlarged size." Preferred embodiments make use of shape memory alloys, [page 5, lines 1-4]. The application focuses on well-known Ni-Ti alloys, which have particularly pronounced shape memory and superelasticity properties [page 5, lines 17-20]. Such Ni-Ti alloys are also referred to as "nitinol" [page 10, lines 17-20].

Claim 22 recites a stent comprising:

a plurality of annular elements, each annular element having a compressed state and an expanded state, wherein each annular element has a longitudinal dimension which is smaller in the radially expanded state than in the compressed state; and

connecting members connecting adjacent annular elements;

wherein the annular elements and connecting members are made of Nitinol, with each connecting member preset with an elasticity which causes the connecting member to elongate longitudinally when the annular elements are in their expanded state to compensate for the smaller longitudinal dimension of the annular elements in the expanded state.

Referring to Figures 11a and 11b, a stent having annular elements and connecting members meeting the structural recitations of claim 22 is shown. In the modified reproduction of those figures shown below, the annular elements are unshaded whereas the connecting elements are shaded:

Fig. 11a

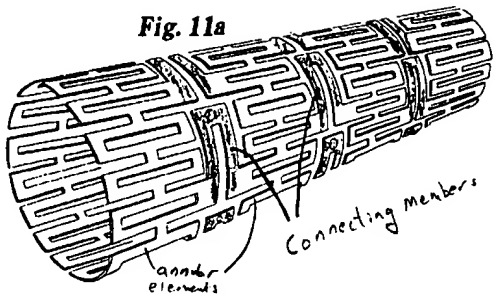
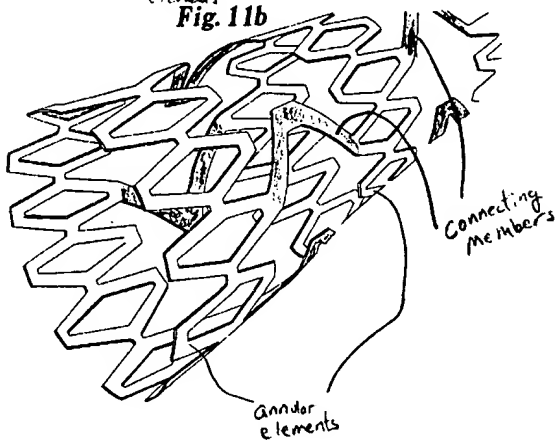


Fig. 11b



Claim 35 pertains to a self-expanding stent of shape memory alloy in two different phase portions, an austenite alloy portion and a martensitic alloy portion arranged so that stent has both an expanded diameter to which the stent self expands and an enlarged stent diameter to which the stent can be deformed by an external force.

(6) Issues

I. Whether the Examiner erred in rejecting claims 22-32, and 34-35 under 35 USC §112 as unsupported by the written description as filed unless a new declaration identifying the present application as a continuation-in-part of its immediate parent is filed.

II. Whether the Examiner erred in rejecting claims 22-32 and 34-35 as anticipated by Roubin, et al, US 5,827,321, filed Feb. 7, 1997.

(7) Grouping of Claims

For issue I, all of the claims on appeal stand or fall together. Claim 22 is representative.

For issue II, claims 22-32 and 34 stand or fall together, claim 22 is representative. Claim 35 stands or falls separately.

(8) Argument

I. The Examiner erred in rejecting claims 22-32, and 34-35 under 35 USC §112 as unsupported by the written description as filed unless a new declaration identifying the present application as a continuation-in-part of its immediate parent is filed.

The failure of the specification to specifically mention a limitation that later appears in the claims is not a fatal one when one skilled in the art would recognize upon reading the specification that the new language reflects what the specification shows has been invented. *All Dental Prodx LLC v. Advantage Dental Products Inc.*, 64 USPQ2d 1945, 1948 (CA FC 2002). In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide *in haec verba* (identical language) support for the claimed subject matter at issue. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570, 39 USPQ2d 1895, 1904 (Fed. Cir. 1996); *In re Wright,* 9 USPQ2d 1649, 1651 (Fed. Cir. 1989). The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Company v. Far-Mar-Co., Inc.*, 227 USPQ 177 (Fed. Cir. 1985).

Drawings alone may provide "written description" of invention required by 35 USC 112 if the drawings show the claimed combination of features. *Vas-Cath Inc. v. Mahurkar,* 19 USPQ2d 1111 (Fed. Cir. 1991).

In the present case it is noted that the immediate parent application, Application No. 08/737,492, corresponds exactly to the application as filed, except for the preliminary amendment which introduced claims 22-34. That is, the abstract, the entire specification, claims 1-21, and all of the drawing figures of the present application are found in the parent application, 08/737,492, which is a §371national stage application of PCT/US95/06228, filed May 18, 1995. The present application is identified as a continuation of application 08/737,492 and a copy of the declaration filed in 08/737,492 has been submitted with the application. Therefore if the features of the rejected claims are supported in any of the abstract, specification, claims and/or drawings they are not new matter first introduced in this application and so requiring a new

declaration.

The Examiner maintains that the parent application did not contemplate presetting the elasticity to elongate as presently recited in claim 22 and further maintains that the stent of Figures 11a and 11b is not taught to be made of nitinol. These objections are erroneous. The rejected claims are clearly supported by the parent application and, as such, are entitled to benefit of the May 18, 1995 PCT filing date of the applicant's parent application. Therefore there was no new matter introduced in claim 22 and so no new declaration is needed.

A. Preset Elasticity of the Fig 11 Stent

The specification, and claims 1-21, describe stents which have 1) a ***deployable*** diameter at less than body temperature, 2) an ***expanded*** diameter larger than the deployable diameter, to which the stent self-expands at body temperature, and a "larger desired expanded" size or "***enlarged***" diameter1 to which the stents may further expand by application of a deformation force (for instance using a balloon) [page 2, lines 5-9, and each original independent claim]. These are characteristics generally of the stents of the invention. Therefore, a statement in the specification that a particular figure depicts a stent of the invention is an express teaching that such stents have these characteristics.

Figures 8-11 depict stents of the invention [page 12, lines 14-16]. As such they are to be understood as having "deployable," "expanded" and "enlarged" diameter configurations.

The application uses the terms "compressed," "constrained," and "deformed to a small diameter" to describe the stent configured at the deployable diameter. In connection with Figures 8-11, the skilled person will readily recognize that this corresponds to the "closed" stents of Figures 8a, 9a, 10a, and 11a, respectively.

The application teaches that the Figures 8b, 9b, 10b and 11b, depict "expanded" configurations of the stents of Figures 8a, 9a, 10a, and 11a, respectively. Since the "expanded" configuration is the configuration of the stents after self-expansion and before balloon deformation, Figure 11b, in particular, is the configuration of the stent of Figure 11a to which the stent self-expands. Moreover, since Figure 11b is not described as depicting a "larger desired

---

1 The claims use the "***enlarged***" diameter term. See also the Abstract ("final enlarged size"). For brevity, we use the "enlarged diameter" from here-on-out.

expanded" or an "enlarged", configuration, it is ***not*** the configuration the stent is still capable of adopting due to balloon deformation.

Self-expansion is caused by a shape memory characteristic built into the stent by various fabrication and manipulation techniques. Shape memory is an elasticity property. With respect to Figure 11a, the stent is preset to self-expand to the configuration of Figure 11b. Thus the patent teaches that the material of the stents of the invention have a ***preset elasticity*** which causes the stent to assume the configuration to which it self-expands. Since Figure 11b depicts the condition to which the stent of Figure 11a self-expands, the stent of Figure 11a has a preset elasticity to assume the condition of Figure 11b.

The preset elasticity of the stent of Figure 11a causes the longitudinal length of the radial bands to decrease and the longitudinal length of the connector to increase. This "necessarily" results from the basic geometry changes which occur as the stent transitions from Figures 11a to 11b, as can be seen from the modified reproduction below where one of the relevant connectors has been highlighted with shading and two angles are labeled:

Fig. 11a

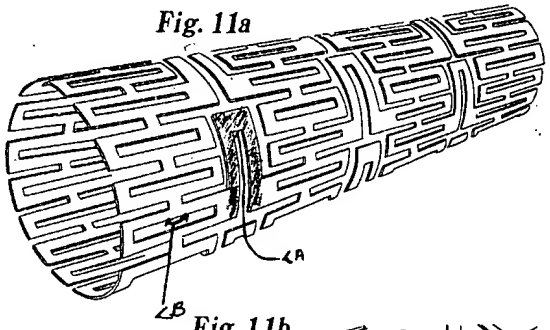
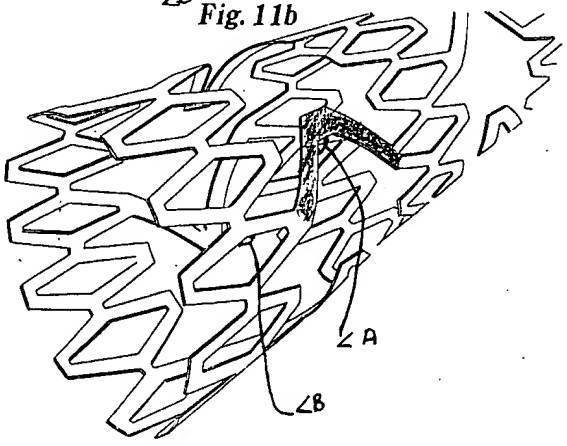


Fig. 11b



In particular, in the modified figures above, because the angle <A enlarges from Fig 11a to 11b,

the total longitudinal length of the connector is longer in Figure 11b. Conversely, because the angle <B in the adjacent annular element decreases from Fig. 11a to Fig. 11b, the longitudinal length of the annular elements necessarily decreases. This is fully evident on the figures themselves. Hence the preset elasticity in the stent of Figure 11a includes a preset elasticity in the connecting member "which causes the connector to elongate longitudinally when the annular elements are in their expanded state to compensate for the smaller longitudinal dimension of the annular elements in the expanded state."

For the reasons just given, Figures 11a and 11b, taken together with the specification disclosure pertaining thereto, teach a stent which fully supports the "preset elasticity" recitation in claim 22. Therefore this feature was not new matter requiring a new declaration.

B. The Fig 11 Stent - Made of Nitinol

The preferred stent material is nitinol [page 2, lines 20-22]. Disclosure of a preference is recognized as clearly supporting its specific inclusion in a claim. *Winter v. Fujita*, 53 USPQ2d 1234, 1247 (USPTO BdPatApp&Int 1999); *Union Oil Co. of California v. Atlantic Richfield Co.*, 54 USPQ2d 1227, 1234 (Fed. Cir. 2000).

Moreover, each original independent claim falls into at least one of the following categories:

i) it directly recites nitinol (nickel-titanium alloy) [claims 16 and 20],

ii) it has a dependent claim which directly recites nitinol [claim 17, dependent 18],

iii) it directly recites austenite and martensite phase properties which the application teaches may be provided with nitinol [claims 9, 15, 17, 21]; or,

iv) it has a dependent claim which directly recites austenite and martensite phase properties which the application teaches may be provided with nitinol [claim 1, dependent 6].

Preferred nitinol alloys are taught, as well as methods for manipulating the nitinol stent material after fabrication of the stent, so as to provide the self-expanded configuration with the intermediate size characteristic of the "expanded" configuration [see page 5, lines 17-20, page 8, line 27 - page 9, line 8]. Nitinol is described as preferred in connection with the embodiments of the invention employing two-discrete components [*e.g.* page 7, lines 7-9]. It is also the specific

material discussed in connection with the non-discrete embodiments of the invention which utilize two-phases of an alloy [pages 10-12]. At least for these reasons, the skilled person reading the parent application will have no doubt that it teaches that the stents of Figures 8-11, may be made of nitinol.

Furthermore, the description of Figures 8-11 immediately follows description of embodiments in which nitinol exists in two phases, but without discrete components for each phase. In discussion of embodiments employing two discrete components, corresponding Figures are provided in which the discrete components are shown and labeled. None of Figures 8-11 describe, label, or appear on their face, to show two components in this manner. These additional factors further guide the skilled person to a specific and certain understanding that the stents of Figures 8-11 are examples of stent configurations which can be fashioned of nitinol according to the discussion of the non-discrete, two-phase alloy embodiments on pages 10-12. As to these embodiments, nitinol alloys are the embodiments specifically exemplified.

Therefore there is no doubt that the parent application taught that the stents prepared in accordance with figures 11a and 11b can be prepared using nitinol. This feature was not new matter requiring a new declaration.

C. Supporting Evidence

The Declaration of Dr. Kaushik Bhattacharya, Professor of Mechanics and Materials at California Institute of Technology, provides confirmatory evidence that a technically skilled person understands the application to teach the specific preset elasticity and nitinol features recited in claim 22. Such testimony is addressed to the understanding of the skilled person in a particular field as to which he has specific and specialized factual knowledge.

Contrary to the assertions of the Examiner, the Bhattacharya Declaration, at paragraph 3, does state the factual basis for Dr. Bhattacharya's conclusions. In particular, Dr. Bhattacharya reviews the stent of Figures 11a and 11b in light of the inventive concepts disclosed in the application and goes to the remainder of the application to determine that those Figures refer to nitinol stents with self-expanding properties corresponding to a preset elasticity.

Thus, the Bhattacharya Declaration explains why one of ordinary skill in the art would have realized that the inventors had possession of the claimed embodiment. It is error to dismiss

such a declaration as providing only conclusory statements or addressing only issues of law. *In re Alton* 37 USPQ 2d 1378 1384 (Fed. Cir 1996)

As we have meticulously demonstrated in parts A and B above, there is a compelling basis in the application for the conclusions which Dr. Bhattacharya reached. The Examiner has no justifiable reason to disregard Dr. Bhattacharya's testimony.

D. The Examiner's Arguments

Against this abundant foundation for the questioned features of claim 22, the Examiner argues that the stent of Figs. 11a and 11b may have been expanded in some way other than by self expansion and/or that it may be made out of material other than nitinol.

The Examiner strangely asserts that the transition from Figure 11a to 11b may be the result of some means, other than a preset elasticity. Unlike Dr. Bhattacharya, the Examiner reads the description of Figures 11a and 11b without regard to the rest of the disclosure and original claims (see item (4) pages 4-6 of the August 19, 2003 Office Action). This reading directly contradicts the express disclosure that these figures depict configurations which may be used in practicing the invention. It is improper.

The application specifically teaches that the "expanded" configuration of the inventive balloons is the state to which the inventive stents self-expand. The stent of Fig 11b is a stent of the invention in the "expanded" configuration. Therefore it is at the configuration to which it self-expands from the configuration of Figure 11a. This is straight-forward, elementary, logic. The Examiner is clearly wrong in suggesting Figure 11b might be understood as representing a condition reached by some other means.

The other assertion, that materials other than nitinol can be used to prepare stent of Figures 11a and 11b, is simply irrelevant to the question of support for claim 22. As we have already shown, the specification teaches the skilled person that the stent of Figs 11a and 11b can be made of nitinol. Such is the only teaching that needs to be considered for support for the recitation of nitinol in claim 22.

It is unreasonable to assert that a skilled person reading the specification as a whole would question whether the application's clear and repeatedly stated preference for nitinol is applicable to the stent of Figures 11a and 11b, simply because the stent might also be prepared

using other materials. Nitinol is taught in the application to be generally useful in the invention. It is the material which the application teaches as exemplary of a recitation found in at least one claim of each claim set of the originally filed claims (*i.e.* a recitation found in each independent claim or in at least one or its dependents). By this method, nitinol is clearly taught as useful in practicing the invention as recited in each of the original independent claims in this application. The existence of alternative materials for some of the disclosed embodiments does not logically detract from the generality of the application's teachings as to the utility of nitinol. Hence, even if the skilled person were, hypothetically, to be confused as to whether the teachings of the non-discrete, two-phase alloy, embodiments were specifically applicable to Figure 11a and 11b, there still would no reasonable basis to question the applicability of the application's teachings regarding the utility of nitinol in fabricating a stent of Figures 11a and 11b.

For the reasons just given, the Examiner's arguments are inadequate to support the outstanding rejection. The rejection of claims 22-32 and 34-35 under 35 USC §112 as unsupported by the written description as filed, unless a new declaration identifying the present application as a continuation-in-part of its immediate parent is filed, should be reversed.

II. The Examiner erred in rejecting claims 22-32, and 34-35 under 35 USC §102(e) as anticipated by Roubin, et al, US 5,827,321.

A. Claims 22-32 and 34

Claims 22-32, and 34 were copied from Roubin, et al, for purposes of provoking an interference. (A declaration of interference with the Roubin et al patent was originally requested in the preliminary amendment filed October 26, 1999). As has already been shown, claims 22-32 and 34-35 are entitled to the benefit of the parent application 08/737,492, which is a §371 national stage application of PCT/US95/06228, filed May 18, 1995. This benefit includes an invention date at least as early as May 18, 1995.

Roubin, et al was filed Feb. 7, 1997. It is not a reference under 35 USC §102(e). It was not filed before the invention of the subject matter of claims 22-32 and 34-35 by the applicant. Therefore, the rejection of claims 22-32 and 34 under 35 USC §102(e) as anticipated by Roubin et al should be reversed.

B. Claim 35

Claim 35 depends from claim 22 and is not anticipated by Roubin et al at least for the reasons given for claims 22-32 and 34. Moreover, claim 35 pertains to a self-expanding stent of shape memory alloy in two different phase portions, an austenite alloy portion and a martensitic alloy portion arranged so that:

> upon transformation of the austenite alloy portion from martensite back to austenite to self-expand the stent back to about the predetermined fabricated diameter at temperatures in excess of the transition temperature of the austenitic superelastic portion, the shape memory of the superelastic austenitic portion tending to form the stent to a larger diameter due to its shape memory but being restrained therefrom by the martensitic alloy portion whereby the austenitic alloy portion can be deformed by external force without plastic deformation along with the martensitic portion to an enlarged stent diameter beyond that of the self-expanded diameter.

That is, the two alloy portions are arranged such that stent has both an expanded diameter to which the stent self expands and an enlarged stent diameter to which the stent can be deformed by an external force.

Roubin does not teach to prepare shape memory stent with two phases to provide for both an expanded diameter to which the stent self expands and an enlarged stent diameter to which the stent can be deformed by an external force. Therefore claim 35 would not be anticipated by Roubin et al even if it were not entitled at least to the benefit of the May 18, 1995 PCT filing date of applicant's parent application 08/737492. For this additional reason, the rejection of claim 35 under 35 USC §102(e) should be reversed.

III. Conclusion

Applicant has demonstrated that support for claim 22 was present in the text of the application as filed in the parent PCT/§371 application 08/737,492 filed May 18, 1995. Therefore, the written description rejection under 35 USC §112 should be reversed. The demonstrated support entitles claim 22 to an invention date at least 20 months prior to the §102(e) date of the Roubin et al patent. Therefore Roubin et al is not a proper reference under 35 USC §102(e) and the anticipation rejection under that statute should also be reversed. The anticipation rejection of claim 35 should also be reversed because Roubin et al does not meet the recitations of a stent having two different phase portions providing both an expanded diameter to

which the stent self expands and an enlarged stent diameter to which the stent can be deformed by an external force.

The application should be remanded for a declaration of interference with Roubin et al, as previously requested by the applicant.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: April 6, 2004

By: _____
Walter J. Steinkraus
Registration No.: 29592

6109 Blue Circle Drive, Suite 2000
Minnetonka, MN 55343-9185
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

f:\wpwork\wjs\04944us04_amd_20040309.doc

Appendix A

CLAIMS ON APPEAL

Claims 1-21 (cancelled)

22. A stent comprising:

a plurality of annular elements, each annular element having a compressed state and an expanded state, wherein each annular element has a longitudinal dimension which is smaller in the radially expanded state than in the compressed state; and

connecting members connecting adjacent annular elements;

wherein the annular elements and connecting members are made of Nitinol, with each connecting member preset with an elasticity which causes the connecting member to elongate longitudinally when the annular elements are in their expanded state to compensate for the smaller longitudinal dimension of the annular elements in the expanded state.

23. The stent of claim 22, wherein each annular element comprises a plurality of alternating struts and apices connected to each other to form a substantially annular configuration.

24. The stent of claim 23, wherein the connecting members are connected to the apices of the adjacent annular members.

25. The stent of claim 23, wherein the plurality of struts comprises left and right struts, with each pair of left and right struts connected to each other at an apex.

26. The stent of claim 23, wherein each strut has a longitudinal dimensional which is smaller when the annular elements are in the expanded state than in the compressed state.

27. The stent of claim 23, wherein each strut has a longitudinal dimensional which is larger when the annular elements are in the compressed state than in the expanded state.

28. The stent of claim 23, wherein at least one of the annular elements is closed such that the

plurality of alternating struts and apices are connected to each other to form a closed annular element.

29. The stent of claim 22, wherein at least one of connecting member has a plurality of alternating segments.

30. The stent of claim 29, wherein the at least one connecting member has a plurality of alternating and angled straight segments.

31. The stent of claim 22, wherein each connecting member has a larger longitudinal dimension when each annular element is in the expanded state than in the compressed state to compensate for the smaller longitudinal dimension of the annular element in the expanded state.

32. The stent of claim 22, wherein each connecting member has a smaller longitudinal dimension when each annular element is in the compressed state than in the expanded state to compensate for the larger longitudinal dimension of the annular element in the compressed state.

33. (cancelled)

34. The stent of claim 22, wherein the annular elements and connecting members define an alternating longitudinal pattern of annular elements and connecting members.

35. The stent of claim 22 comprising, at about normal body temperatures, a shape-memory, superelastic, austenitic alloy portion and a shape memory, martensitic alloy portion, the superelastic austenitic alloy portion having a transition temperature from martensite to austenite less than body temperature while the martensitic alloy portion has a transition temperature from martensite to austenite greater than body temperature, the martensitic alloy portion and superelastic austenitic alloy portion being constructed, arranged and associated with respect to each other in comprising the stent such that the two alloy portions act in combination to allow, upon transformation of the austenitic alloy portion to martensite at a temperature below the

transition temperature, constraint of the stent to a deployment diameter smaller than the predetermined fabricated diameter and upon transformation of the austenite alloy portion from martensite back to austenite to self-expand the stent back to about the predetermined fabricated diameter at temperatures in excess of the transition temperature of the austenitic superelastic portion, the shape memory of the superelastic austenitic portion tending to form the stent to a larger diameter due to its shape memory but being restrained therefrom by the martensitic alloy portion whereby the austenitic alloy portion can be deformed by external force without plastic deformation along with the martensitic portion to an enlarged stent diameter beyond that of the self-expanded diameter.